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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,013	11/16/2001	Shui-on Leung	IMMU-014US2	7681
37013 7590 04/23/2009 ROSSI, KIMMS & McDOWELL, LLP. 20609 Gordon Park Square, Suite 150 Ashburn, VA 20147				
EXAMINER				
BLANCHARD, DAVID J				
ART UNIT		PAPER NUMBER		
1643				
MAIL DATE		DELIVERY MODE		
04/23/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

09/988,013

**Applicant(s)**

LEUNG ET AL.

**Examiner**

David J. Blanchard

**Art Unit**

1643

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 28, 29, 31 and 32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28, 29, 31 and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Claims 1-27, 30 and 33-43 are cancelled.
2. Claims 28-29 and 31-32 are pending and under consideration.
3. This Office Action contains New Grounds of Rejections.

***Specification***

4. The disclosure is objected to because of the following informalities:

Applicants' amendment to paragraph [0001] of the specification, "Cross-Reference to Related Applications" filed 6/30/2005 is noted, however, in view of the prosecution history of the instant application and the decision by the Board of Patent Appeals and Interferences (BPAI) mailed 13 March 2009, applicant is requested to verify that the instant application is a CIP as amended on 6/30/2005 or a direct continuation of US Application No. 08/289,576 as noted at pg. 8 of the BPAI decision.

Additionally, applicant should update the status of US Application No. 09/741,843 filed December 22, 2000, which is now abandoned. 37 C.F.R. 1.121.

Appropriate correction is required.

***Priority***

5. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

In view of the decision by the Board of Patent Appeals and Interferences mailed 13 March 2009, the disclosure of the prior-filed application, Application No. 08/289,576, filed August 12, 1994, provides adequate written descriptive support for the claimed invention in the manner provided by the first paragraph of 35 U.S.C. 112. Accordingly, the effective filing date of instant claims 28-29 and 31-32 is deemed to be August 12, 1994, the filing date of Application No. 08/289,576.

*Claim Rejections - 35 USC § 102*

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 28-29 and 31-32 are rejected under 35 U.S.C. 102(a) as being anticipated by Harris et al (WO 94/09136, published 4/28/1994).

The claims are drawn to a method of designing amino acid sequences of variable domains of a humanized monoclonal antibody comprising: (a) comparing the amino acid sequences of the light and heavy chain variable domains of a monoclonal antibody to be humanized with the amino acid sequences of the light and heavy chain variable domains of two or more human antibodies; (b) selecting framework regions from a first human antibody for the light chain and from second and third human antibodies for the heavy chain based on the sequence comparison, wherein the heavy chain FR1, FR2 and FR3 are selected from the second human antibody and FR4 is selected from the third human antibody; and (c) incorporating the framework regions selected in step (b) with the corresponding light and heavy chain complementarity determining regions (CDRs) of the monoclonal antibody to be humanized, to design humanized light and heavy chain variable domain amino acid sequences wherein the heavy chain FR4 is selected from the human NEWM antibody, the light chain framework regions are selected from the human REI antibody, and the heavy chain FR1, FR2 and FR3 are selected from the human EU antibody and retaining selected HCMV16 framework amino acid residues predicted to have contacts with the CDRs or within a 4.5 Angstrom radius of any atoms within a CDR of the humanized HCMV16 antibody. Further the method comprises (d) preparing DNA sequences encoding the humanized light and heavy chain variable domain amino acid sequences; (e) operably incorporating the variable domain DNA sequences into at least one vector comprising DNA sequences encoding the constant domains of the human light and heavy chain regions; (f) introducing the at least one vector into a cell; and (g) culturing the cell containing the at least one vector under conditions to produce the humanized monoclonal antibody.

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Harris et al teach a method of designing humanized heavy and light chain variable domain amino acid sequences of murine monoclonal antibody HCMV16 comprising comparing the light and heavy chain variable domain sequences of HCMV16 with the light and heavy chain sequences of two or more human antibodies, wherein the human REI light chain frameworks are selected and the human EU heavy chain frameworks are selected for FR1, FR2 and FR3 and human NEWM heavy chain FR4 was selected and the selected human REI, EU and NEWM frameworks are incorporated with the corresponding light and heavy chain CDRs of HCMV16 and the amino acid residues immediately before heavy chain CDRs 1 and 3 of HCMV16 were retained in the humanized HCMV16 antibody (i.e., residues contacting the CDRs and within a 4.5 Angstrom radius of any atoms within the CDRs). Harris et al also teach preparing the DNA sequences encoding the designed humanized HCMV16 light and heavy chain variable domain amino acid sequences, operably incorporating the prepared humanized light chain variable domain sequence into the pSV<sub>hyg</sub> expression vector comprising the human kappa constant region and the prepared humanized heavy chain variable domain sequence into the pSV<sub>gpt</sub> expression vector comprising the human IgG1 constant region, transfecting mammalian cells (NSO cells) with the light and heavy chain vectors and culturing the cells under conditions to produce the humanized HCMV16 antibody (see entire document, particularly Example 1 at pg. 13-24, specifically pg.18, lines 10-25, pg. 22 and 24).

Thus, Harris et al anticipates the claims.

8. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832.

The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Blanchard/  
Primary Examiner, A.U. 1643

/Larry R. Helms/  
Supervisory Patent Examiner, Art Unit 1643

/JOHN L. LEGUYADER/  
Director, Technology Center 1600